



## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

**Importer of Controlled Substances Application: Fisher Clinical Services, Inc.**

**[Docket No. DEA-392]**

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part

1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on May 5, 2017, Fisher Clinical Services, Inc., 7554 Schantz Road, Allentown, Pennsylvania 18106 applied to be registered as an importer of the following basic classes of controlled substances:

<b>Controlled Substance</b>	<b>Drug Code</b>	<b>Schedule</b>
Methylphenidate	1724	II
Levorphanol	9220	II
Noroxymorphone	9668	II
Tapentadol	9780	II

The company plans to import the listed controlled substances for analytical research, testing, and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

The company plans to import an intermediate form of tapentadol (9780) to bulk manufacture tapentadol for distribution to its customers. Placement of these (this) drug code(s) onto the company’s registration does not translate into automatic approval of subsequent permit applications to import controlled substances. Approval of permit applications will occur only when the registrant’s business activity is consistent with

what is authorized under to 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: August 28, 2017

Demetra Ashley,  
*Acting Assistant Administrator.*  
Billing Code 4410-09-P

[FR Doc. 2017-18785 Filed: 9/5/2017 8:45 am; Publication Date: 9/6/2017]